

## **REMARKS**

Claims 1-3, 5-12 and 21-25 were examined. Applicants amend claim 1 and submit no additional claims. Applicants have amended claim 1 as recommended by the Examiner to overcome Gambale.

The Patent Office rejects claims 1-3, 6, 8, 11, 12 and 21-24 under 35 U.S.C. §102(e) and claims 5, 7, 9, 10 and 25 under 35 U.S.C. §103(a). Reconsideration of the pending claims is respectfully requested in view of the above amendment and the following remarks.

### **A. 35 U.S.C. §102 and §103: Rejection of the Claims**

The Patent Office rejects claims 1-3, 6, 8, 11, 12 and 21-24 under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,248,112 to Gambale et al. ("Gambale"). The Patent Office rejects claims 5, 7, 9, and 10 under 35 U.S.C. §103(a) as being unpatentable over Gambale. Claim 25 is rejected under 35 U.S.C. §103(a) as unpatentable over Gambale as modified by U.S. Patent No. 4,299,230 to Kubota et al. ("Kubota").

Applicants have amended claim 1 as recommended by the Examiner to overcome Gambale. Applicants submit that amended independent claim 1 is not disclosed by or taught by Gambale for at least the reason that Gambale does not disclose or teach a needle with a first opening to and in fluid communication with a lumen of the needle and a second opening to and in fluid communication with the same lumen of the needle, and a fluid pressure measurement to measure a second pressure when the first opening becomes occluded, and a third pressure when an aperture of the second opening becomes occluded, as required by amended claim 1.

Gambale teaches multiple pressure ports spaced along a distal end of a device, where each port is monitored through individual lumens extending through the tube and in communication with monitoring device 31 (see column 7, line 66 through column 8, line 5).

Consequently, Gambale does not teach a first and second opening to and in fluid communication with the same lumen, so that a second pressure can be measured when the first opening becomes occluded, and a third pressure can be measured when an aperture of the second opening becomes occluded, as required by claim 1.

Moreover, it can be appreciated that by having both openings to and in fluid communication with the same lumen of the needle, embodiments described in the application, for example, without limitation thereto provide at least the benefit of using a single lumen to inject a therapeutic agent and to sense penetration depth during injection, by injecting the agent into tissue using the second opening while measuring the second pressure of the fluid being injected to sense that the first opening is occluded due to penetration (e.g. see at least claims 1, 3, 6 and 11; and paragraphs 30-32 and 35; and Figs. 1-3B of the application). On the other hand, this is not taught or possible in Gambale.

In addition to being dependent upon allowable base claim 1, Applicants disagree with the rejection of claim 25 for at least the reason that the cited references do not teach a visual indicator or audio feedback system that indicates to an operator (1) to advance a needle in response to measuring no significant change in pressure as compared to the first pressure, (2) to proceed with the advancement of the needle slowly in response to measuring the significant increase in pressure as compared to the first pressure, and (3) to stop the advancement of the needle in response to the significant increase in pressure as compared to the second pressure, as required by claim 25. Kubota simply teaches a pressure sensor array along the length of a device so that depending on how deep the device is inserted, each sensor of the array will either sense pressure, or will not sense pressure (see Fig. 11, column 1, lines 20-40 and column 4, lines 24-49). Thus, Kubota only responds to each sensor either sensing a first pressure, or a different second pressure, but does not teach the above noted first, second, and significant increase as compared to the second pressure, as required by claim 25.

In addition to being dependent upon allowable base claims, Applicants disagree with the rejection of the dependent claims for at least the reason noted above.

Hence, for at least the reasons noted above, Applicants respectfully request the Patent office withdraw all of the rejections of the claims.

### CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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#### CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

  
Jessica Huester

2010-01-04  
Date